K083252

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510(k) Summary
NuTorque Programmable Electric System
October 14, 2008

FEB 18 2009

Company:

DentalEZ Inc., StarDental Division
Owner/operator number 2520265

Contact Person:

Dale Braas
Quality Manager
DentalEZ Inc., StarDental Division
1816 Colonial Village Lane
Lancaster, PA 17601
Phone: (717) 291-1161, ext. 4308
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Proprietary/Trade Name:

NuTorque Programmable Electric System

Common/Usual Name:

Dental Handpiece

Classification:

Controller, Foot, Handpiece and Cord (per 21 CFR 872.4200)

Predicate Device:

Ti-Max NL400 manufactured by Nakanishi, Inc. Japan. (K011926)

Device Description:

The NuTorque Programmable Electric System is an electric handpiece system for use in performing various dental procedures including grinding and trimming, post and pin drilling, pin setting, finishing, polishing, endodontic, caries removal and prophylaxis.

The NuTorque Programmable Electric System is composed of a power supply, control unit, cable and brushless micromotor. The control unit controls the torque, speed and directional rotation of the motor. The system is programmed through the use of a color touch screen on the control unit. The motor has a rotational speed of 100- 40,000 rpm's and can be operated in a clockwise or counterclockwise direction. The system also provides variable light intensity to the handpiece.

Intended Use:

The NuTorque Programmable Electric System is used by trained dental professionals to perform general dental procedures including crown preparation, cavity preparation, crown finishing, inlay and the filling, polishing, prophylaxis and endodontic treatment.

The device is a control unit which drives a low voltage dc electric micromotor via a handpiece hose. Power is supplied to the control unit by an ac power supply. The speed of the motor is controlled by the foot control of the dental unit. ISO E-type attachments are used to perform the various procedures. The maximum free run speed of the micromotor is 40,000 rpm's.

Technological Characteristics:

The NuTorque Programmable Electric System is composed of a control unit, power supply, cable and brushless micromotor. The system can be custom programmed with 5 custom settings in the endodontic mode and 3 custom settings in the preparation mode. Within these custom settings there are 27 available gear and torque ratio combinations available. The system also has a demo mode which allows the operator to verify the selected settings for illumination, fiber optic delay, display contrast, autoreverse-forward and speaker prior to working on the patient. Performance testing was conducted to validate the safety and effectiveness of the NuTorque Programmable Electric System. This testing included the electrical safety, electromagnetic compatibility and validation and verification of the software. Testing was completed in accordance with recognized consensus standards.

Substantial Equivalence:

The determination of substantial equivalence is based on the premise that the proposed devices and the predicate devices have the same intended use, and similar technology and design. Both devices have the same means of operation and are used for the same procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 8 2009

DentalEZ Incorporated, StarDental Division
C/o J.A. Van Vugt
KEMA Quality B.V.
Utrechtseweg 310
Arnhem
Netherlands NL-6812 AR

Re: K083252
Trade/Device Name: NuTorque Programmable Electric System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: February 2, 2009
Received: February 3, 2009

Dear Mr. Braas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083252

Device Name: NuTorque Programmable Electric System

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083252